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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,288	04/27/2000	Edward Nathaniel Hanley JR.	8151-24A	3083

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,288	HANLEY ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,37-51,53-56 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,37-51,53-56 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/04 has been entered. It is again noted that no interference can be declared until claims are found allowable.

2. The rejection of claims 35 & 37-38 under 35 U.S.C. 112, first paragraph, as containing new matter is withdrawn due to the amendment of the claims.

3. The rejection of claims 37 & 38 under 35 U.S.C. 112, second paragraph for no proper antecedent basis for the recitation of "therapeutic composition" is withdrawn due to the amendment of the claims.

4. The rejection of claims 39 & 52 for no proper antecedent basis for the recitation of "said cultured disc tissue" is withdrawn due to the amendment or cancellation of the claim.

5. The rejection of claims 39, 41, 45, 47 & 51 & 52 for no proper antecedent basis for the recitation of "obtain an explant" is withdrawn due to the amendment of the claims.

6. The rejection of claims 41 & 54 for "mincing…intervertebral cells" is withdrawn due to the amendment of the claims.

7. The rejection of claims 35, 37-38 & 47-51 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn due to Applicants' arguments after the amendment of the claims.

8. Applicant's arguments filed 2/17/04 have been fully considered but they are not deemed to be persuasive.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 35, 37-51 & 53-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using therapeutic compositions comprising "early childhood" human intervertebral disc cells and a carrier that contain required and defined cell stimulants/growth factors/carrier molecules to aid in the treatment of human disc diseases or injuries, does not reasonably provide enablement for uses of such cells from adolescents or adults wherein annulus and/or nucleus cells no longer exist, or for compositions missing required/ defined components or comprising carrier derivatives thereof (i.e., in that none of the claims recite each and every required component). The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 3 (mailed 9/13/00), 7 (mailed 5/09/01), 16 (mailed 5/21/02) and 22 (mailed 10/16/03), and as follows.

In contrast to Applicants' arguments on pages 8-11 of the response, the issue remains that the current claims cannot work in adolescents or adults wherein annulus and/or nucleus cells no longer exist, as previously made of record. Arguments related to what Guilack et al., Aigner et al., Frick et al. and Luk et al. also additionally teach in their research articles does not address this issue, or whether these undefined cells reasonably can "treat human disc diseases" (especially when the specification fails to define what population of disc cells to use or how). As previously made of record, the type of matrix made by disc cells is dependent on the environment these cells are placed within and on the type of disc cells used, which the claims fail to fully define. Again, as previously made of record, disc cells are a heterogeneous population of cells with different intrinsic variations in their responses to mechanical stimuli, with distinct biosynthetic capabilities, where what constitutes a successful regenerative processes is unclear within the art, and in which the instant specification fails to provide guidance toward overcoming these intrinsic problems in generating a potential successful "treat[ment of] human disc diseases". In other words, this is an "enablement" rejection, where one of skill in the art does not reasonably know how to use Applicants' invention, as currently claimed, and where arguing that these references do not anticipate the instant invention is not on point.

11. Claims 39-51, 54 & 58 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 22 (mailed 10/16/03), and as follows.

In contrast to Applicants' assertions on page 12 of the response, it remains confusing how it is envisioned to "treat... a diseased or injured invertebral (*sic*- still misspelled) disc *having nucleus and annulus regions"* when *normal development* (or disease or injury) destroys these two regions which are *only* normally present in healthy early childhood tissue (i.e., as it relates to claim 39). In other words, Applicants' arguments make little sense. It is further noted that each application is examined according to its own merits.

No antecedent basis remains for the recitation of "said cultured human intervertebral disc tissue" (i.e., as it relates to claim 49 & now also claim 47). No proper antecedent basis now exists for the recitation of "said intervertebral disc tissue" in claim 41, and also in claims 47 & 46 where another "said human intervertebral disc tissue", "said isolated human intervertebral disc tissue" and/or "said cultured human intervertebral disc cells", as well as an another "said isolated disc tissue", "said intervertebral disc tissue" are recited (i.e., as it relates to claims 41-51 & 54), which only further confuses what exact tissue is being referenced in any of these claims due to the inconsistency in the current claim language.

12. Claims 53-56 & 58 stand rejected under 35 U.S.C. 102(a) as being anticipated by Chelberg et al (J. Anat. 186: 43-53 (1995)), for the reasons made of record in Paper No: 3 (mailed 9/13/00), 16 (mailed 5/21/02) & 22 (mailed 10/16/03), and as follows.

Applicants argue on pages 15-16 of the response that "[t]he cells were digested in fetal bovine serum and cast in alginate microspheres. *Pages 44-45*. No carrier was present. No growth factors were present." However, in contrast to Applicants' assertions, both "alginate microspheres" (i.e., as it especially relates to claim 58) and "fetal bovine serum" (i.e., as it also relates to claim 58) are carriers, by definition, and where these claims further require "no growth factor" in the claimed composition; thereby, meeting all recited claim limitations for the reasons previously made of record. Therefore, Applicants' arguments are not persuasive, because process steps used to obtain a product are immaterial to what constitutes the product, itself, for the reasons extensively made of record.

In summary, Chelberg et al teach the claimed **product** of "cultured disc tissue" "with a carrier", for the reasons previously made of record; consistent with that held by the courts in *In re Thorpe* and *In re Marosi* previously made of record.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
May 6, 2004
post. sg.
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